

REMARKS

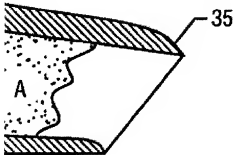
The Applicants respectfully request reconsideration of this application in view of the above amendments and the following remarks.

35 U.S.C. § 112 Rejection, First Paragraph

Claims 1 and 8 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

(1) In rejecting claim 1, the Examiner has asserted that there is no disclosure support for “a portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip.”

Applicants respectfully submit that there is disclosure support for these limitations. Claim 1 as originally filed included “a portion of the shaft including the second point defining a tip (emphasis added).” Paragraph [0028] discloses in part “Microcatheter 10 also includes angled or beveled opening 34 angled 0 to 60 degrees (angle γ (emphasis added)), in this case opposite the above-referenced deflection angle α .” Paragraph [0029] discloses in part “A point at the distal end of shaft 25 representing the greatest length of shaft 25 defines tip 35. A portion of the body of shaft 25 including tip 35 may be beveled in a direction opposite bevel angle (emphasis added) to yield a more refined cutting tool.” Support is also found in the portion of FIG. 11 reproduced below.



Accordingly, Applicants respectfully request that the rejection of claim 1 be withdrawn.

- (2) As amended, claim 8 recites *“The catheter of claim 6, wherein the deflection angle is in a direction opposite the first direction.”*

Support for claim 8 is found at least in original claim 8, which recites *“The catheter of claim 6, wherein the deflection angle is in a direction opposite the first direction”* Support for claim 8 is also found in paragraph [0028] which discloses in part *“Distal end 33 includes bend portion 39 such that an axis of symmetry through bend portion 39 is deflected at an angle (α) (emphasis added) between 0 and 60 degrees, preferably 10 and 15 degrees from an axis of symmetry defined by the proximal portion of shaft 25 (in this case deflected upward as viewed). Microcatheter 10 also includes angled or beveled opening 34 angled 0 to 60 degrees (angle γ), in this case opposite the above-referenced deflection angle α (emphasis added).”*

Accordingly, Applicants respectfully request that the rejection of claim 8 be withdrawn.

35 U.S.C. §103(a) Rejection – Gobby, Bacich

Claims 1-18 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,474,576 issued to Gobby (hereinafter “Gobby”) and further in view of U.S. Patent No. 5,472,419 issued to Bacich (hereinafter “Bacich”). Without admitting that these references could or should be combined, the Applicants respectfully submit that the present claims are allowable over Gobby and Bacich.

Claim 1 recites:

“A catheter comprising:

a shaft comprising a body with a proximal portion and a distal portion, the body having a length configured for placement through an endoscopic device in an assisted embryo transfer procedure and the body defining an opening from the proximal portion to the distal portion, the distal portion having an exterior dimension suitable for insertion into a body of a subject as a procedural instrument for transferring an embryo, the distal portion having an end that is beveled in a first direction across the opening, such that a length of the shaft

to a first point on the end is a first length and a length of the shaft to a second point on the end is a second length longer than the first length, a portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip shaped to be inserted into an endometrial lining of the subject, and wherein the tip comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject.”

Gobby and Bacich do not disclose these limitations or render them obvious.

Firstly, Gobby and Bacich do not disclose or render obvious that “a portion of the shaft including the second point is beveled in a second direction opposite the first direction **defining a tip shaped to be inserted into an endometrial lining of the subject.**”

The Examiner appears to have relied upon FIG. 2 of Bacich to reject the portion of the shaft including the second point beveled in the second direction opposite the first direction. See e.g., the bottom of page 3 through the top of page 4 of the present Office Action.

However, Bacich does not disclose or render obvious “**a tip shaped to be inserted into an endometrial lining of the subject.**” In fact, Bacich appears to **teach away** from a tip shaped to be inserted into tissue of a subject. At column 2, lines 26-38, Bacich states “*To reduce the likelihood of trauma, the distal end of the transfer catheter is preferably substantially blunt (emphasis added).*” Similarly, at column 4, line 54, Bacich states “*The distal end 25 is blunt (emphasis added).*” FIGs. 2 and 6 of Bacich clearly show rounded corners, apparently to make them more blunt. FIGs. 4, 5, 8, and 12 of Bacich clearly show that the catheter is not inserted into the tissue. Accordingly, Bacich does not disclose or render obvious “**a portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip shaped to be inserted into an endometrial lining of the subject.**”

Moreover, it would be inappropriate for the Examiner to merely disregard some or all of these limitations on the grounds that they are believed to be functional. Even if some or all of these limitations are regarded as functional, they are not properly rejected unless the limitations are found to be “**inherent (emphasis added)**” in a prior art reference. See e.g., MPEP Section 2114. In the

instant case, the limitations *“to be inserted into an endometrial lining of the subject”* is not inherent in Bacich because the structure in Bacich does not define *“a tip shaped to be inserted into an endometrial lining of the subject.”* Moreover, Bacich explicitly teaches that *“the distal end of the transfer catheter is preferably substantially blunt (emphasis added).”*

Accordingly, for at least this reason, claim 1 is believed to be allowable over Gobby and Bacich.

Secondly, Gobby and Bacich do not disclose or render obvious that *“the tip comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject”*.

Neither Gobby or Bacich discloses that the apparatus or catheter is to penetrate the endometrial lining, let alone that the apparatus or catheter includes a tip comprising a material having the claimed rigidity and flexibility characteristics.

Moreover, Gobby and/or Bacich may mention polymeric or other materials of which the apparatus or catheters are to be constructed. However, Applicants respectfully submit that this, by itself, is not sufficient to reject the claimed rigidity and flexibility characteristics of the material recited in claim 1. It is well known that the rigidity and flexibility of polymeric materials depends not only on the particular polymer, but also on other factors, such as, for example, density, average molecular weight, formation conditions, etc. Neither Gobby or Bacich mention that the apparatus or catheter is to penetrate the endometrial lining and resist penetrating the uterine muscle. Accordingly, it is not inherent that the materials mentioned in Gobby or Bacich have the particular densities, average molecular weights, formation conditions, or the like, to achieve the particular rigidity and flexibility characteristics of the material as recited in claim 1.

For at least one or more of these reasons, claim 1, and its dependent claims, are believed to be allowable over Gobby and Bacich.

Independent claim 11 recites at least “*the angled tip has a shape that is suitable for insertion into an endometrial lining of the subject and comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject*”. Accordingly, independent claim 11, and its dependent claims, are believed to be allowable for one or more reasons similar to those discussed above for claim 1.

Independent claim 34 recites at least “*a microsurgical instrument at the distal portion, the microsurgical instrument including an end of the distal portion that is beveled across the opening to form an angled tip, the angled tip shaped for insertion into an endometrial lining*.” Accordingly, independent claim 34 is believed to be allowable for one or more reasons similar to those discussed above for claim 1.

Dependent Claims Believed to be Even More Allowable

Claim 26 recites “*the distal portion is pointed*.” Gobby and Bacich do not disclose these limitations or render them obvious.

Claim 28 recites “*the tip comprises a cutting tool*.” Gobby and Bacich do not disclose these limitations or render them obvious.

Claim 29 recites “*the distal portion comprises a microsurgical instrument capable of being inserted into the endometrial lining*.” Gobby and Bacich do not disclose these limitations or render them obvious.

Claim 32 recites “*the tip comprises a cutting tool capable of being inserted into the endometrial lining*.” Gobby and Bacich do not disclose these limitations or render them obvious.

Conclusion

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the cited art of record and are in condition for allowance. Applicants respectfully request that the rejections be withdrawn and the claims be allowed at the earliest possible date.

Request For Telephone Interview

The Examiner is invited to call Brent E. Vecchia at (303) 740-1980 if there remains any issue with allowance of the case.

Request For An Extension Of Time

The Applicants respectfully petition for an extension of time to respond to the outstanding Office Action pursuant to 37 C.F.R. § 1.136(a) should one be necessary. Please charge our Deposit Account No. 02-2666 to cover the necessary fee under 37 C.F.R. § 1.17 for such an extension.

Charge Our Deposit Account

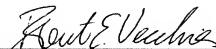
Please charge any shortage to our Deposit Account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: September 9, 2009

By



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